flow to just ripple the top of the benzene solution. When the benzene is removed (as determined by a constant volume of hexadecane) add 5 milliliters of isooctane and evaporate. Repeat once to insure complete removal of benzene. Remove the beaker and cover with aluminum foil (previously rinsed with hexane) until cool.

Quantitatively transfer the hexadecane residue to a 5-milliliter volumetric flask and dilute to volume with isooctane. Determine the absorbance of the solution in 1-centimeter path length cells between 280 and 400 millimicrons using isooctane as a reference. Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without a sample. If the corrected absorbance does not exceed the limits prescribed in paragraph (b)(1)(ii) of this section, the sample meets the ultraviolet absorbance specifications for hydrocarbon solvent.

(c) Synthetic fatty alcohols may be used as follows:

(1) As substitutes for the corresponding naturally derived fatty alcohols permitted in food by existing regulations in this part or part 173 of this chapter provided that the use is in compliance with any prescribed limitations.

(2) As substitutes for the corresponding naturally derived fatty alcohols used as intermediates in the synthesis of food additives and other substances permitted in food.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 11837, Mar. 19, 1982; 49 FR 10105, Mar. 19, 1984; 54 FR 24897, June 12, 1989]

§ 172.866 Synthetic glycerin produced by the hydrogenolysis of carbohydrates.

Synthetic glycerin produced by the hydrogenolysis of carbohydrates may be safely used in food, subject to the provisions of this section:

(a) It shall contain not in excess of 0.2 percent by weight of a mixture of butanetriols.

(b) It is used or intended for use in an amount not to exceed that reasonably required to produce its intended effect.

§ 172.867 Olestra.

Olestra, as identified in this section, may be safely used in accordance with the following conditions:

(a) Olestra is a mixture of octa-, hepta-, and hexa-esters of sucrose with fatty acids derived from edible fats and oils or fatty acid sources that are generally recognized as safe or approved for use as food ingredients. The chain lengths of the fatty acids are no less than 12 carbon atoms.

(b) Olestra meets the following specifications:

(1) The total content of octa-, hepta-, and hexa-esters is not less than 97 percent as determined by a method entitled ''Determination of Olestra by Size Exclusion Chromatography,'' dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(2) The content of octa-ester is not less than 70 percent as determined by a method entitled ''Measurement of the Relative Ester Distribution of Olestra Test Material'' dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(3) The content of hexa-ester is not more than 1 percent as determined by the method listed in paragraph (b)(2) of this section.

(4) The content of penta-ester is not more than 0.5 percent as determined by the method listed in paragraph (b)(2) of this section.

(5) The unsaturated fatty acid content is not less than 25 percent (thus not more than 75 percent saturated

fatty acid) and not more than 83 percent as determined by a method entitled ''Measurement of the Fatty Acid Composition of Olestra Test Material,'' dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(6) The content of C12 and C14 fatty acids is each not more than 1 percent, and total C20 and longer fatty acids is not more than 20 percent. C16 and C18 fatty acids make up the remainder with total content not less than 78 percent as determined by the method listed in paragraph (b)(5) of this section.

(7) The free fatty acid content is not more than 0.5 percent as determined by a method entitled ''Free Fatty Acids'' published in the *Official Methods and Recommended Practices of the American Oil Chemists' Society*, 3d Ed. (1985) vol. 1, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the American Oil Chemists Society, 1608 Broadmoor Dr., Champaign, IL 61821, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(8) The residue on ignition (sulfated ash) is not more than 0.5 percent.

(9) Total methanol content is not more than 300 parts per million as determined by the ''Total Available Methanol Method,'' dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740 or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(10) The total heavy metal content (as Pb) is not more than 10 parts per million.

(11) Lead is not more than 0.1 part per million, as determined by a method entitled ''Atomic Absorption Spectrophotometric Graphite Furnace Method,'' Food Chemicals Codex, 3d Ed. 3d Supp. p. 168 (1992), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Research Council Press, 2101 Constitution Ave. NW., Washington, DC, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(12) Water is not more than 0.1 percent, as determined by a method entitled ''Moisture,'' *Official Methods and Recommended Practices of the American Oil Chemists' Society*, 4th Ed. (1989), vol. 1, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the American Oil Chemists Society, 1608 Broadmoor Dr., Champaign, IL 61821, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(13) Peroxide value is not more than 10 meq/kg as determined by a method entitled ''Peroxide Value,'' *Official Methods and Recommended Practices of the American Oil Chemists' Society*, 4th Ed. (1989) vol. 1, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the American Oil Chemists Society, 1608 Broadmoor Dr., Champaign, IL 61821, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register,

800 North Capitol Street, NW., suite 700, Washington, DC.

(14) The stiffness is not less than 50 kiloPascals/second, as determined by a method entitled ''Method for Measurement of the Stiffness of Olestra,'' dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) Olestra may be used in place of fats and oils in prepackaged ready-to-eat savory (i.e., salty or piquant but not sweet) snacks. In such foods, the additive may be used in place of fats and oils for frying or baking, in dough conditioners, in sprays, in filling ingredients, or in flavors.

(d) To compensate for any interference with absorption of fat soluble vitamins, the following vitamins shall be added to foods containing olestra: 1.9 milligrams alpha-tocopherol equivalents per gram olestra; 51 retinol equivalents per gram olestra (as retinyl acetate or retinyl palmitate); 12 IU vitamin D per gram olestra; and 8 µg vitamin K_1 per gram olestra.

(e)(1) Vitamins A, D, E, and K present in foods as a result of the requirement in paragraph (d) of this section shall be declared in the listing of ingredients. Such vitamins shall not be considered in determining nutrient content for the nutritional label or for any nutrient claims, express or implied.

(i) An asterisk shall follow vitamins A, D, E, and K in the listing of ingredients;

(ii) The asterisk shall appear as a superscript following each vitamin;

(iii) Immediately following the ingredient list an asterisk and statement, ''Dietarily insignificant'' shall appear prominently and conspicuously as specified in §101.2(c) of this chapter;

(2) Olestra shall not be considered as a source of fat or calories for purposes of §§101.9 and 101.13 of this chapter.

(f) Consistent with its obligation to monitor the safety of all additives in the food supply, including olestra, the Food and Drug Administration will review and evaluate all data and information bearing on the safety of olestra received by the agency after the effective date of this regulation, and will present such data, information, and evaluation to the agency's Food Advisory Committee within 30 months of the effective date of this regulation. The purpose of such presentation will be to receive advice from the Committee on whether there continues to be reasonable certainty that use of olestra in compliance with this regulation is not harmful. The agency will hold such additional Food Advisory Committee meetings on olestra as the agency determines, in its discretion, to be necessary. Based upon the results of this entire process, the FDA will initiate any appropriate regulatory proceedings.

[61 FR 3171, Jan. 30, 1996; 61 FR 11546, Mar. 21, 1996, as amended at 68 FR 46402, Aug. 5, 2003]

§ 172.868 Ethyl cellulose.

The food additive ethyl cellulose may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is a cellulose ether containing ethoxy (OC_2H_5) groups attached by an ether linkage and containing on an anhydrous basis not more than 2.6 ethoxy groups per anhydroglucose unit.

(b) It is used or intended for use as follows:

(1) As a binder and filler in dry vitamin preparations.

(2) As a component of protective coatings for vitamin and mineral tablets.

(3) As a fixative in flavoring compounds.

§ 172.869 Sucrose oligoesters.

Sucrose oligoesters, as identified in this section, may be safely used in accordance with the following conditions:

(a) Sucrose oligoesters consist of mixtures of sucrose fatty acid esters with an average degree of